



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 870

[Docket No. FDA-2022-N-0713]

### Medical Devices; Cardiovascular Devices; Classification of the Coronary Artery Disease Risk Indicator Using Acoustic Heart Signals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the coronary artery disease risk indicator using acoustic heart signals into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the coronary artery disease risk indicator using acoustic heart signals' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

**DATES:** This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on November 24, 2020.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2531, Silver Spring, MD, 20993-0002, 301-796-6017, [Kimberly.Crowley@fda.hhs.gov](mailto:Kimberly.Crowley@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the coronary artery disease risk indicator using acoustic heart signals as class II (special controls), which we have determined will provide a reasonable

assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under

section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

## II. De Novo Classification

On November 4, 2019, FDA received Acarix A/S’s request for De Novo classification of the CADScor System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has

determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 24, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.1420.<sup>1</sup> We have named the generic type of device coronary artery disease risk indicator using acoustic heart signals, and it is identified as a device that records heart sounds including murmurs and vibrations to calculate a patient-specific risk of presence of coronary artery disease, as an aid in cardiac analysis and diagnosis.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Coronary Artery Disease Risk Indicator Using Acoustic Heart Signals Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation, Labeling, and Usability testing
Skin burn/irritation	Electrical safety testing, and Electromagnetic compatibility testing
False positive leading to unnecessary medical procedures	Software verification, validation, and hazard analysis; Usability testing; Acoustic performance testing; Clinical performance testing; and Labeling
False negative leading to failure to detect coronary artery disease	Software verification, validation, and hazard analysis; Usability testing; Acoustic performance testing; Clinical performance testing; and Labeling
Delay in calculation due to device failure resulting in a delay of treatment	Software verification, validation, and hazard analysis; Clinical performance testing; Usability testing; Acoustic performance testing; and Labeling

---

<sup>1</sup> FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

### III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

### **List of Subjects in 21 CFR Part 870**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

**PART 870--CARDIOVASCULAR DEVICES**

1. The authority citation for part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 870.1420 to subpart B to read as follows:

**§ 870.1420 Coronary artery disease risk indicator using acoustic heart signals.**

(a) *Identification.* A coronary artery disease risk indicator using acoustic heart signals is a device that records heart sounds including murmurs and vibrations to calculate a patient-specific risk of presence of coronary artery disease, as an aid in cardiac analysis and diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must fulfill the following:

(i) Testing must include a discussion of the patient population and any statistical techniques used for analyzing the data; and

(ii) Testing must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(2) Acoustic performance testing must evaluate microphone sensitivity, sound acquisition bandwidth, and amplitude accuracy. The acoustic sensor specifications and mechanism used to capture heart sounds must be described.

(3) A scientific justification for the validity of the algorithm(s) must be provided. This justification must fulfill the following:

(i) All inputs and outputs of the algorithm must be fully described;

(ii) The procedure for segmenting, characterizing, and classifying the acoustic signal must be fully described; and

(iii) This justification must include verification of the algorithm calculations and validation using an independent data set.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Human factors/usability testing must demonstrate that the user can correctly use the device, including device placement, based solely on reading the directions for use.

(7) Performance data must demonstrate the electromagnetic compatibility and electrical safety of the device.

(8) Labeling must include the following:

(i) A description of what the device measures and outputs to the user;

(ii) Instructions for proper placement of the device;

(iii) Instructions on care and cleaning of the device;

(iv) Warnings identifying sensor acquisition factors that may impact measurement results and instructions for mitigating these factors; and

(v) The expected performance of the device for all intended use populations and environments.

Dated: May 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-11699 Filed: 5/31/2022 8:45 am; Publication Date: 6/1/2022]